



## Testimony

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# MEDICARE

## Challenges Remain in Setting Payments for Medical Equipment and Supplies and Covered Drugs

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Accountability \* Integrity \* Reliability

## Report Documentation Page

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Mr. Chairman and Members of the Subcommittee:

I am pleased to be here as you discuss Medicare payment methods related to durable medical equipment, prosthetics, orthotics, and supplies—products referred to in this statement as medical equipment and supplies—and covered outpatient drugs. Over the years, we and the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) have periodically reported that Medicare has paid higher than market rates for various medical equipment and supply items and often considerably higher than provider acquisition costs for Medicare-covered outpatient drugs.<sup>1</sup> Since the late 1980s, the Congress has enacted a series of legislative changes affecting payment methods and payment adjustment authority for medical equipment and supplies and outpatient drugs. However, the progress made in setting appropriate rates has been mixed, owing, in part, to various constraints faced by the agency responsible for administering Medicare—the Centers for Medicare and Medicaid Services (CMS), formerly called the Health Care Financing Administration (HCFA).<sup>2</sup>

In this regard, my remarks today will focus on (1) Medicare’s experience in setting payment rates for medical equipment and supplies and outpatient drugs; (2) certain changes designed to assist in setting payments for medical equipment and supplies and outpatient drugs incorporated in the Balanced Budget Act of 1997 (BBA);<sup>3</sup> and (3) lessons learned from efforts to improve the appropriateness of Medicare’s payments. My comments are based primarily on our previously issued work.

In summary, because of the program’s size, scope, and role as a public payer, Medicare has limited options to set and adjust payments for medical equipment and supplies and outpatient drugs. For example, in cases where Medicare is the dominant payer for a service or product, the program’s share of the payments can distort the market, making reliance on market prices problematic. Medicare’s method of paying for medical equipment and supplies is through fee schedules that remain tied to suppliers’

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<sup>1</sup>A list of related GAO products is included at the end of this statement.

<sup>2</sup>This statement will refer to HCFA in discussing actions taken before the agency’s name was officially changed on July 1, 2001.

<sup>3</sup>Pub. L. No. 105-33, 111 Stat. 251.

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historical charges to Medicare rather than market prices. Similarly, Medicare's method of determining outpatient drug payments is based on list prices, not prices that purchasers actually pay for the outpatient drugs. Medicare's payment approaches lack flexibility to keep pace with market changes, and as a result, Medicare often pays higher prices than other public payers for medical equipment and supplies and outpatient drugs.

Despite dramatic instances of wide disparities in market prices and Medicare's payment rates for medical equipment and supplies and outpatient drugs, Medicare is not in a position to take prompt action. To lower unreasonably high payment rates, it must follow a lengthy and complicated regulatory process for making payment adjustments. The BBA gave HCFA authority to use a streamlined process to adjust payment rates for most medical equipment and supplies and outpatient drugs.<sup>4</sup> However, the agency's attempt to use this authority drew intense industry criticism, in part because the agency acted before it responded to public comment on how it would implement the authority. The Congress then prohibited use of either the original or streamlined processes until public comments are addressed and a final rule issued.<sup>5</sup> To date, a final rule has not been published, effectively precluding the use of the original or streamlined processes to adjust Medicare payment rates, where excessive. Nevertheless, the BBA also provided HCFA the authority to test an alternative to setting prices administratively.<sup>6</sup> This authority permitted HCFA to conduct demonstrations, for a limited number of items at a few locations, using competition to determine an appropriate payment for these items. In this process, suppliers competed for the right to supply certain items on the basis of quality and price. Two such demonstrations have reported savings without any measurable problems in beneficiary access.

Past efforts to lower Medicare's overly generous payments suggest several lessons. First, payment changes are most effectively implemented when the process used to set or adjust a rate is defensible. Medicare's size and impact on the nation's health care economy means that its payment methods and rate adjustments, no matter how reasonable, will face close

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<sup>4</sup>BBA at § 4316, 111 Stat. 390 (codified at 42 U.S.C. § 1395u(b)(8) and (9) (Supp. III 1997)).

<sup>5</sup>Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113, App. F, § 223, 113 Stat. 1501, 1501 A-352 (to be codified at 42 U.S.C. 1395u(b)(8) (Supp. V 1999)).

<sup>6</sup>BBA at § 4318, 111 Stat. 392 (codified at 42 U.S.C. § 1395w-3 (Supp. III 1997)).

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scrutiny. As a result, the need for CMS to collect sufficient information on market prices and potential effects on suppliers and beneficiaries before taking action is paramount. A second lesson, related to the first, is that the information on Medicare claims for medical equipment and supplies is not specific enough to enable CMS to determine which products Medicare is actually paying for. Thus, the agency has difficulty trying to use market prices to set appropriate rates. A third lesson is that for the foreseeable future, CMS will have to continue to rely on fee schedules based on historical charges in setting payment rates for medical equipment and supply items. The recent demonstrations that set payments for items through competitive bidding were instructive, but the positive results achieved may be neither applicable nor practical on a wider scale for many products.

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## Background

CMS, an agency within HHS, is responsible for much of the federal government's multi-billion-dollar payments for health care, primarily through the Medicare and Medicaid programs. Medicare—the nation's largest health insurance program—covers about 40 million elderly and disabled beneficiaries. Medicaid is a state-administered health insurance program, jointly funded by the federal and state governments, that covers eligible low-income individuals including children and their parents, and aged, blind, and disabled individuals. Each state administers its own program and determines—under broad federal guidelines—eligibility for, coverage of, and reimbursement for, specific services and items.

Most Medicare beneficiaries purchase part B insurance, which helps pay for certain physician, outpatient hospital, laboratory, and other services; medical supplies and durable medical equipment (such as oxygen, wheelchairs, hospital beds, and walkers); and certain outpatient drugs. Medicare part B pays for most medical equipment and supplies using a series of fee schedules. Medicare pays 80 percent, and the beneficiary pays the balance, of either the actual charge submitted by the supplier or the fee schedule amount, whichever is less. Generally, Medicare has a separate fee schedule for each state for most categories of items, and there are upper and lower limits on the allowable amounts that can be paid in different states to reduce variation in what Medicare pays for similar items in different parts of the country.

The fee schedules specify a Medicare-allowable payment amount for each of about 1,900 groups of products. Each product group is identified by a Healthcare Common Procedure Coding System (HCPCS) Level II code, and all products grouped under a code are intended to be items that are

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alike and serve a similar health care function. For example, one code (E1130) describes a standard wheelchair with fixed arms. Many different brands can be billed under this code, so long as they fit the basic description.

Medicare part B also covers roughly 450 outpatient drugs—generally those that cannot be self-administered and are related to physicians services, such as cancer chemotherapy, or are provided in conjunction with covered durable medical equipment, such as inhalation drugs used with a nebulizer.<sup>7</sup> In addition, Medicare part B covers selected immunizations and certain outpatient drugs that can be self-administered, such as blood clotting factors and some oral drugs used in association with cancer treatment and immunosuppressive therapy.

To administer Medicare part B fee-for-service claims, CMS contracts with insurance companies, referred to as carriers, who review and pay claims that have been submitted by physicians and other outpatient providers and suppliers. To ensure appropriate payment, carriers conduct claims reviews that determine, for example, whether the services claimed are covered by Medicare, are reasonable and necessary, and have been billed with the proper codes.

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## Payment Approaches Lack Flexibility to Keep Pace with Market Changes

Medicare's size and complexity make it extremely challenging to develop payment methods that prudently reimburse providers while promoting beneficiary access to items and services. As Medicare's steward, CMS cannot passively accept what providers want to charge the program. However, because of its size, Medicare profoundly influences health care markets. Medicare is often the dominant payer for services and products, and in such cases, it cannot rely on market prices to determine appropriate payment amounts because Medicare's share of payments distorts the market. In addition, Medicare has had difficulty relying on competition to determine prices. Because of constraints on excluding any qualified provider from participating in the program, Medicare traditionally includes all such providers who want to participate. Finding ways of encouraging competition without excluding some providers—a normal leverage that purchasers use to make competition work—has been problematic. As a result, Medicare has had to administratively set payment

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<sup>7</sup>A nebulizer is a device driven by a compressed air machine that allows the patient to take medicine in the form of a mist or wet aerosol.

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amounts for thousands of services and items, trying to do so in ways that encourage efficient delivery, while ensuring beneficiary access to them.

Adding to the complexity of setting payment amounts is Medicare's status as a highly visible public program with certain obligations that may not be consistent with efficient business practices. For example, CMS is constrained from acting swiftly to reprice services and supplies even when prevailing market rates suggest that payments should be modified. When making substantive changes, Medicare's enabling legislation generally requires public input. This minimizes the potential for actions to have unintended consequences. However, seeking and responding to public input from various provider and supplier groups can be a time-consuming process that can sometimes thwart efficient program management.

Prior to 1987, Medicare payments for medical equipment and supplies were based on supplier charges, subject to some limitations. As part of their responsibilities to administer Medicare claims, individual Medicare carriers raised or lowered payments to suppliers in their local areas to align them with market prices. When carriers sought to adjust payments on this basis, they employed a process that involved gathering relevant pricing data from local area markets, determining new payment levels on the basis of the price information obtained, and notifying area suppliers of the changes. Although HCFA monitored carriers' performance in carrying out these steps, it did not evaluate the appropriateness of the new payment levels established.

In 1987, the Congress and HCFA began the process of moving the Medicare program from paying on the basis of individual providers' charges for medical equipment and supplies and covered outpatient drugs, to developing payment methods intended to pay more prudently through use of program-determined amounts. Specifically, the Congress introduced fee schedules for medical equipment and supplies in 1987.<sup>8</sup> Statewide fees were determined on the basis of average supplier charges on Medicare claims allowed in each state in 1986 and 1987, and were updated for

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<sup>8</sup>Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4062, 101 Stat. 1330, 1330-101 (codified at 42 U.S.C. § 1395m (1988)). Certain medical equipment and supply items not originally on a fee schedule were added later—for example, surgical dressings, were added by the Omnibus Budget Reconciliation Act of 1993 Pub. L. No. 103-66, § 13544(b), 107 Stat. 312, 589 (codified at 42 U.S.C. § 1395m(i) (1994)).

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inflation in some years.<sup>9</sup> However, the agency lacked mechanisms to otherwise adjust fees to reflect marketplace changes. As a result, disparities between fee schedule amounts and market prices developed over time, and Medicare significantly overpaid for some medical equipment and supplies.

In recent years, we and the HHS OIG reported on instances where Medicare payments for certain medical equipment and supplies and outpatient drugs were excessive compared with retail and other prices. One notable example of excessive Medicare payments is included in our 1995 report on surgical dressings.<sup>10</sup> We estimated that Medicare could have saved almost \$20 million in 1995 if it had paid the lowest wholesale prices available in a national catalog for 44 types of surgical dressings. Although Medicare's fee schedule for surgical dressings was based on medians of retail prices found in supply catalogs when the schedule was set, Medicare's statute did not permit HCFA to lower the fee schedule when retail prices for dressings decreased.<sup>11</sup>

Another instance of excessive Medicare payment was for home oxygen equipment and supplies provided to patients with pulmonary insufficiency. Medicare fee schedule allowances for home oxygen were significantly higher than the rates paid for almost identical services by the Department of Veterans Affairs (VA), which in fiscal year 1995 paid for home oxygen benefits for over 23,000 patients. In 1997, we estimated that Medicare

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<sup>9</sup>Prior to 1998, these fees were adjusted each year using formulas tied to the Consumer Price Index. No update was provided from 1998 through 2000 or in 2002, although updates were provided in 2001. 42 U.S.C. § 1395m(a)(14) (Supp. IV 1998); Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113, App. F, § 228, 113 Stat. 1501, 1501A-356; and Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, App. F, § 425, 114 Stat. 2763, 2763A-519 (to be codified at 42 U.S.C. § 1395m(a)(14)).

<sup>10</sup>U.S. General Accounting Office, *Medicare: Excessive Payments for Medical Supplies Continue Despite Improvements*, [GAO/HEHS-95-171](#) (Washington, D.C.: Aug. 8, 1995).

<sup>11</sup>Authority to adjust payment rates that were excessive did not extend to surgical dressings and certain other medical supplies at that time. The BBA extended the authority to adjust rates for any payments under part B that are excessive. BBA at § 4316, sec. 1842(b)(8)(A)(i)(I), 111 Stat. 390 (changing "application of this subsection" to "application of this part"). Clarifying this broadened scope, "application of this part" was later changed to "application of this title to payment under this part." Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113, App. F, § 223(c), 113 Stat. 1501, 1501A-353.



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could have saved over \$500 million in fiscal year 1996 if it had paid rates for home oxygen comparable to those paid by VA.<sup>12</sup>

Medicare's payments for outpatient drugs have been similarly excessive, although the methodology used to determine payment amounts is somewhat different and attempts to tie Medicare's payments to market prices. In 1989, the Congress required that physician services be paid based on fee schedules beginning in 1992.<sup>13</sup> The fee schedules developed by HCFA to comply with this requirement provided for all outpatient drugs furnished to Medicare beneficiaries not paid on a cost or prospective payment basis to be paid based on the lower of the estimated acquisition cost or the national average wholesale price (AWP).<sup>14</sup> Manufacturers report AWP to organizations that publish them in drug price compendia, which are typically updated annually, and Medicare carriers base providers' payments on these published AWP.

In concept, such a payment method has the potential to be market-based and self-adjusting. The reality is, however, that AWP is neither an average nor a price that wholesalers charge. Because the term AWP is not defined in law or regulation, there are no requirements or conventions that AWP reflect the price of any actual sale of drugs by a manufacturer. Given the latitude manufacturers have in setting AWP, Medicare's payments are often not related to market prices that physicians and suppliers actually pay for the products.

A June 1997 House Budget Committee report accompanying the bill that became the BBA, in explaining the reason for specifying a 5-percent reduction from AWP, cited a report by the HHS OIG regarding Medicare payments for outpatient drugs.<sup>15</sup> Among the OIG findings were that Medicare payments ranged from 20 percent to nearly 1,000 percent of certain oncology drugs' commercially available prices.

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<sup>12</sup>The savings estimate includes adding a 30-percent adjustment to VA payment rates to account for differences between the Medicare and VA programs. See U.S. General Accounting Office, *Medicare: Comparative Information on Medicare and VA Patients, Services, and Payment Rates for Home Oxygen*, [GAO/HEHS-97-151R](#) (Washington, D.C.: June 6, 1997).

<sup>13</sup>Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6102, 103 Stat. 2106, 2169 (codified at 42 U.S.C. § 1395w-4 (Supp. I 1989)).

<sup>14</sup>56 *Fed. Reg.* 59,502, 59,507 (Nov. 25, 1991).

<sup>15</sup>H.R. Rep. No. 105-149, at 1354 (1997).

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Our recent work found that Medicare payments in 2001 for part B-covered outpatient drugs remained significantly higher than prices widely available to physicians and pharmacy suppliers.<sup>16</sup> For example, most physician-administered drugs had widely available discounts ranging from 13 to 34 percent below AWP. Two other physician-administered drugs had discounts of 65 and 86 percent. Pharmacy suppliers—the predominant billers for 10 of the high-expenditure and high-volume drugs we analyzed—also purchased drugs at prices considerably lower than Medicare payments. For example, two inhalation drugs accounting for most of Medicare payments to pharmacy suppliers had widely available discounts averaging 78 percent and 85 percent from AWP.

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## BBA Reforms Sought to Improve Medicare's Ability to Set Appropriate Rates

Despite such dramatic illustrations of disparities between Medicare payments and prices widely available to others acquiring medical equipment and supplies and covered outpatient drugs, Medicare has not had the tools to respond quickly in such instances. Carriers used to adjust payment amounts as part of their responsibility to appropriately pay Medicare claims, but in 1987, the Congress effectively prohibited use of this process to lower Medicare payment rates until 1991.<sup>17</sup> In 1988, the Congress required use of a more formal “inherent reasonableness” process that could be accomplished only by HCFA, not by the carriers.<sup>18</sup> In other reports, we have described this process as slow and cumbersome and have noted that it is not available for some items, such as surgical supplies.<sup>19</sup> Since 1991, when HCFA was first permitted to use the inherent reasonableness process to adjust payments for medical equipment and supplies, it successfully did so only once—for blood glucose monitors—

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<sup>16</sup>U.S. General Accounting Office, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost*, [GAO-01-1118](#) (Washington, D.C.: Sept. 21, 2001).

<sup>17</sup>Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4062(b), 101 Stat. 1330, 1330-100.

<sup>18</sup>Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360, § 411(g)(1)(B)(xiii), 102 Stat. 683, 782. These procedures were previously applicable only to any inherent reasonableness review with respect to physician services. 42 U.S.C. 1395m(a)(10)(B) (1988).

<sup>19</sup>Changing an unreasonable payment level required, among other things, a formal notice-and-comment rulemaking process that involved the HCFA Administrator, the Secretary of Health and Human Services, and the Director of the Office of Management and Budget (OMB). U.S. General Accounting Office, *Medicare Payments: Use of Revised “Inherent Reasonableness” Process Generally Appropriate*, [GAO/HEHS-00-79](#) (Washington, D.C.: July 5, 2000) and [GAO/HEHS-95-171](#).

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and in that instance took almost 3 years to adjust the maximum allowable Medicare payment from \$185.79 to \$58.71.

In 1997, in response to concerns about HCFA's difficulties in adjusting payment rates determined to be excessive, the Congress included a provision in the BBA that gave HCFA authority to use a streamlined inherent reasonableness process to adjust payments for medical equipment and supplies and covered outpatient drugs by up to 15 percent a year.<sup>20</sup> Subsequent legislation required that a final regulation taking into account public comments be published before the agency could use any inherent reasonableness authority. Because the agency has not issued the final regulation, it cannot adjust Medicare's fee schedules to respond to market price information. The BBA also provided HCFA with opportunities to test an alternative to setting rates administratively that could be more responsive to market prices.<sup>21</sup> This alternative is competitive bidding—a process allowing suppliers to compete for the right to supply their products on the basis of established criteria, such as quality and price.<sup>22</sup>

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### Streamlined Process to Adjust Fees Needs Further Regulatory Action to Be Implemented

The BBA gave HCFA authority to use a streamlined inherent reasonableness process for part B services (excluding physician's services). Under this authority, HCFA can adjust payments by up to 15 percent per year using a streamlined process, or can use its original process with formal notice and comment to make larger adjustments. In January 1998, the agency published an "interim final rule with comment period" for the streamlined inherent reasonableness process that became effective 60 days after it was published.<sup>23</sup> This was a departure from the usual practice of first responding to public comments before issuing a final regulation.

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<sup>20</sup>BBA at § 4316, 111 Stat. 251, 390.

<sup>21</sup>BBA at § 4319, 111 Stat. 251, 392. (Codified at 42 U.S.C. § 1395w-4 (Supp. III 1997).

<sup>22</sup>In the competitive bidding demonstration projects authorized under BBA, Medicare part B items and services (other than physician services) were furnished under competitively awarded contracts. For each demonstration product or service, the prices bid by winning suppliers were used to determine the competitively bid fee schedule price.

<sup>23</sup>63 *Fed. Reg.* 687 (Jan. 7, 1998). In this interim final rule, HCFA committed to having a notice and comment period for any payment adjustments, even through the streamlined process.

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Under the interim final rule, HCFA delegated authority to use the streamlined process to the Medicare carriers that process claims for medical equipment and supplies, with final action on payment adjustments to be approved by the agency. The carriers attempted to lower maximum payment rates for eight groups of products, gathering information on retail prices through surveys conducted in at least 16 states. In September 1998, the carriers notified suppliers of proposed adjustments for eight groups of products and solicited comments. Industry groups representing various medical equipment and supply manufacturers and suppliers expressed serious concerns about how the inherent reasonableness process was implemented and whether the surveys were conducted properly. The Congress requested that we review the appropriateness of implementing the streamlined inherent reasonableness authority through an interim final rule and the soundness of the carriers' surveys. Pending the results of our review, HCFA suspended the carrier-proposed payment reductions in March 1999.

In November 1999, the Congress passed legislation prohibiting HCFA or the carriers from using any inherent reasonableness authority until we issued our report and the agency issued a final rule taking into account our findings and public comment.<sup>24</sup> In our July 2000 report, we concluded that, while the carriers could have conducted their surveys more rigorously, the surveys and other evidence sufficiently justified the carriers' proposed payment reductions for five of eight product groups.<sup>25</sup> In our report, we recommended that HCFA clarify criteria for using its inherent reasonableness authority, strengthen agency or carrier survey methodology in the future, collect additional data on prices for the other three product groups before adjusting their payment amounts, and monitor beneficiary access after any payment changes. Although our report is almost 2 years old, CMS has not issued a final regulation that would allow it to use either its streamlined or original inherent reasonableness processes to adjust Medicare payment amounts for part B supplier-billed services. Thus, the agency lacks a tool to adjust its fee schedules, short of statutory changes.

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<sup>24</sup>Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113, App. F, § 223, 113 Stat. 1501, 1501A-352 (signed into law January 29, 1999).

<sup>25</sup>[GAO/HEHS-00-79](#).

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## BBA Provisions Authorized Competitive Bidding Demonstration Projects

In order to experiment with other ways of setting Medicare's payments for medical equipment and supplies and outpatient drugs, the BBA provided authority for HCFA to conduct demonstration projects using competitive bidding and to include home oxygen in at least one of the demonstrations.<sup>26</sup> Evidence from two competitive bidding projects suggests that, for most of the items selected, competition might provide a tool that facilitates setting more appropriate payment rates and result in program savings.

In its first competitive bidding demonstration, conducted in Polk County, Florida, HCFA set rates for oxygen, hospital beds, surgical dressings, enteral nutrition and supplies, and urological supplies through competitive bidding. HCFA reported that the new rates set by this competitive process in the Florida demonstration saved Medicare an average of 17 percent on the cost of these medical equipment and supply items without compromising beneficiary access to these items.<sup>27</sup>

In a second demonstration in San Antonio, Texas, the agency included oxygen; hospital beds; manual wheelchairs; noncustomized orthotic devices, including "off-the-shelf" items such as braces and splints; and albuterol sulfate and other nebulizer drugs. Preliminary CMS information on the San Antonio competitive bidding demonstration identified an average savings of 20 percent, without any negative effects on beneficiary access.

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## Past Efforts to Correct Inappropriate Payments Suggest Lessons for The Future

Whether attempting to adjust payments administratively or through competitive bidding, CMS can only be effective if it has a defensible process for doing so and accurate information upon which to base action. Any change to Medicare's payments, particularly a reduction in fees for medical equipment and supplies or covered outpatient drugs, should be accompanied by an ongoing assessment of whether the new payments adequately support Medicare beneficiaries' access to such items and services and properly reimburse providers and suppliers. Such monitoring

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<sup>26</sup> BBA at § 4219, 111 Stat. 392. The BBA at 4552(a), 111 Stat. 459, also reduced home oxygen payment amounts by 25 percent effective January 1, 1998, and an additional 5 percent effective January 1, 1999.

<sup>27</sup> Medicare program savings did not occur in all product categories; there were higher prices for surgical dressings, one of five product categories in the demonstration.

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needs to examine current experience so that prompt fee adjustments can be made if access problems are found.

Efforts to lower excessive payment rates through the inherent reasonableness process illustrate the difficulties CMS has in making even minor adjustments, as the agency's actions can have wide ramifications for providers, suppliers, and beneficiaries. When HCFA tried to use its streamlined inherent reasonableness authority in 1998 to reduce payment rates for various medical equipment and supply items and outpatient drugs, it attempted to take action before responding to public comment, thereby leaving the effort open to criticism. In addition, we concluded that the carriers' survey methodology was not rigorous enough to provide a basis to adjust fees nationally for all of the products under review.

What the agency lacked was sufficient information on market prices. Such information, along with current local, as well as national, data on beneficiaries' use of services and program expenditures, is key to setting rates administratively. Because HCFA did not have reliable acquisition cost information, its carriers engaged in a very labor-intensive information-gathering effort.

One major problem CMS has when going to the marketplace to collect information is that it cannot determine the specific products Medicare is paying for when carriers process claims for medical equipment and supplies. Carriers pay claims on the basis of billing codes indicating that the supplied items belong to a particular product group. These groups can cover a broad range of product types, quality, and market prices. As a result, products that differ widely in properties, use, performance, and price are billed under the same code and the program pays the same amount. For example, we reported in 1998 that catheters belonging to a single product category varied in type and price, from about \$1 to \$18, with Medicare's maximum fee payments ranging across states from \$9.95 to \$11.70.<sup>28</sup> However, HCFA had no information on which catheters were being provided to beneficiaries.

To address the problem of insufficient specificity, we recommended in the 1998 report that suppliers be required to include universal product numbers (UPN) as well as current billing codes on claims. UPNs and

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<sup>28</sup>U.S. General Accounting Office, *Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies*, [GAO/HEHS-98-102](#) (Washington, D.C.: May 12, 1998).

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associated bar codes are increasingly used to identify specific medical equipment and supplies, similar to the way universal product codes are used in supermarkets. Manufacturers can use bar codes for each product to identify characteristics such as the manufacturer, product type, model, size, and unit of packaging. Using UPNs—or some other mechanism—incorporated into claim forms to bring more specificity to what is provided to beneficiaries could help CMS better determine appropriate payments.

Under provisions in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), HHS has adopted standards for coding medical services, procedures, and equipment and supplies.<sup>29</sup> These provisions were aimed at simplifying data reporting and claims processing requirements across all public and private payers. Under the standards, HCPCS Level II was designated as the code set for medical equipment and supplies. Its limitation in specificity argues for evaluating whether the current code set can be adjusted to better distinguish between various products currently grouped within a single HCPCS Level II code.

Lack of specificity has been a similar problem for the codes used to define inpatient hospital procedures. The HIPAA standard code set for reporting hospital inpatient procedures is the International Classification of Disease, 9th Edition, Clinical Modification, Volume 3 (ICD-9 CM Vol. 3). The inadequacy of this code set is widely recognized, as it lacks both the specificity to accurately identify many key aspects of medical procedures as well as the capacity to expand in order to appropriately incorporate codes in response to new technology. In fact, HHS recognized that in adopting the ICD-9-CM Vol. 3 as a HIPAA standard, the agency would need to replace it, given the code set's limitations. As a consequence, CMS plans to implement a new code set, the International Classification of Disease, 10th Edition, Procedural Coding System (10 PCS), which would provide much greater specificity.

Our work on payments for covered outpatient drugs, which identified strategies used by other payers to obtain prices closer to acquisition costs, underscores the value of accurate information for determining appropriate payments. For example, the VA uses the leverage of federal purchasers to secure verifiable information on actual market transactions by private purchasers—specifically, the prices that drug manufacturers charge their “most-favored” private customers. To enable the VA to determine the

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<sup>29</sup>Pub. L. No. 104-191, § 262(a), § 1173(c), 110 Stat. 1936, 2025.

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most-favored-customer price, by statute, manufacturers who wish to sell their products to the federal agencies involved are required to provide information on price discounts and rebates offered to domestic customers and the terms and conditions involved, such as length of contract periods and ordering and delivery practices.<sup>30</sup> The manufacturers provide this information and agree to offer the VA and other government purchasers drugs at these prices, subject to VA audit of their records,<sup>31</sup> in order to have state Medicaid programs cover their drugs.

This type of information could be helpful in setting payment amounts for certain Medicare drugs. It is already available to CMS, but for use only in the Medicaid—not the Medicare—program.<sup>32</sup> With congressional approval, CMS could use the information provided to Medicaid to determine appropriate prices for Medicare that would be based on actual prices being paid in the market. One key step would be to determine the formula to use to calculate payments based on the price data. Most likely, Medicare would not set payments to match the prices paid by most favored customers but would need to pay closer to average market prices to ensure access for all beneficiaries and adequate payments to providers.

Results from the competitive bidding demonstrations suggest that competition can also serve as a tool to obtain more appropriate prices for medical equipment and supplies and outpatient drugs. By competing a small number of products and limiting the geographic area of competition, CMS took steps to manage the process, which included monitoring of beneficiary access and product quality. In its fiscal year 2003 budget, the Administration proposed expanding competitive bidding for medical

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<sup>30</sup>38 U.S.C. § 8126 (1994).

<sup>31</sup>The VA negotiates prices for and purchases medical equipment, supplies, and drugs through the Federal Supply Schedule. Federal Supply Schedule prices are available to any federal agency that directly procures pharmaceuticals or medical equipment and supplies, including VA medical centers, the Department of Defense, the Bureau of Prisons, the Public Health Service, and other designated entities such as the District of Columbia, U.S. territorial governments, the Indian Health Service, and some state veterans homes.

<sup>32</sup>Under a provision of the Omnibus Budget Reconciliation Act of 1990 (OBRA), state Medicaid programs receive rebates from manufacturers based on either the manufacturer's "best price" to a private purchaser or the average price (including cash discounts and other price reductions) paid to drug manufacturers by U.S. wholesalers for certain drugs. In order to have their drugs covered by Medicaid, manufacturers must be willing to provide the rebate and price information to calculate it. § 1927 of the Social Security Act, added by OBRA 1990, Pub. L. No.101-508, § 4401, 104 Stat. 1388, 1388-143 (1990) (classified to 42 U.S.C. Sec. 1396r-8).



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equipment and supplies nationally, which it estimates could save \$240 million in fiscal year 2003 and \$5 billion over 10 years.

The Administration's expansion proposal to translate these limited demonstrations into a competition involving a larger number of products nationally would be a substantial undertaking and may not be practical or appropriate for all products. CMS would require new authority to begin to use competitive bidding outside of a demonstration. A key element to the new authority would be the extent to which and the basis whereby providers could be excluded from Medicare. While Medicare normally allows any qualified provider to participate in the program, competitive bidding may be most effective only by limiting the number of providers or suppliers who could provide items or services. For example, in the Polk County demonstration, only 16 out of the 30 bidders were selected to participate. Limiting the number of participating suppliers obviously has an effect on both beneficiaries and suppliers. While provider participation is not an entitlement, the effects of exclusion—in terms of numbers of providers and the volume of services affected—need to be identified and assessed. Similarly, for some products, who the provider is may be of little consequence for the beneficiary, but for others, maintaining greater beneficiary choice and direct access to the provider could be important.

Whether payment rates are set or adjusted through competitive bidding or administrative fee-setting, monitoring to ensure that beneficiaries continue to have access to the items or services is a critical component of such efforts. For example, when the Congress reduced Medicare home oxygen payment rates by 25 percent effective January 1, 1998, and an additional 5 percent effective January 1, 1999, it wanted assurance that beneficiaries could continue to receive satisfactory service.<sup>33</sup> To evaluate the impact of the home oxygen payment reduction on access and quality, the BBA

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<sup>33</sup>For beneficiaries who receive oxygen at home, Medicare part B pays suppliers a fixed monthly fee per beneficiary that covers a stationary, home-based oxygen unit and all related services and supplies, such as tank refills. There is a separate fixed monthly fee for a portable unit, if one is prescribed. Medicare's oxygen payment method is called "modality neutral" because the payment rate is the same regardless of the type of oxygen delivery system prescribed, i.e. compressed gas, liquid oxygen, or oxygen concentrator.

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required studies conducted by us and HHS.<sup>34</sup> Neither study found any significant access problems with the payment reduction. In addition, home oxygen was included in both competitive bidding demonstrations, and through those demonstrations, prices were reduced further. HCFA estimated that Medicare's home oxygen payments were reduced by 16 percent in the Polk County demonstration, without beneficiary access problems. Such monitoring is important, not just when required by statute but as part of an ongoing effort to ensure the Medicare program is effectively serving its beneficiaries.

Unfortunately, such studies to review the effects of payment reductions on access are the exception. As we have reported before, CMS has not been able to generate data that are timely, accurate, and useful on payment and service trends essential to effective program monitoring.<sup>35</sup> One of the principal lessons to be drawn from the many BBA payment reforms is that newly implemented policies need a thorough assessment of their effects. Policy changes, particularly those that constrain payment, almost inevitably spark calls for revisions. Considerations of such revisions need to be based on sufficient information so that, at one extreme, policies are not unduly affected by external pressures and premature conclusions as to their impact, and at the other extreme, policies do not remain static when change is clearly warranted.<sup>36</sup> CMS has not been well-positioned to collect and analyze data regarding beneficiaries' use of services—information that is essential to managing the program effectively.<sup>37</sup> This year's 5.4 percent reduction of physicians' fees from what was paid in 2001 raised concerns about beneficiaries' access. While prior information available on physicians' willingness to see Medicare beneficiaries did not indicate

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<sup>34</sup>U.S. General Accounting Office, *Medicare: Access to Home Oxygen Largely Unchanged; Closer HCFA Monitoring Needed*, [GAO/HEHS-99-56](#) (Washington, D.C.: Apr. 5, 1999) and Rebecca Olson, Carolyn Harper, Stephanie Lui, and others. *Report on Peer Review Evaluation of Home Oxygen Equipment*. California Medical Review, Inc. (San Francisco, Calif.: Sept. 30, 2000). This HHS study analyzed 1996 and 1998 claims data to calculate the number of Medicare oxygen prescriptions, and also conducted 1999 surveys of physicians, suppliers, and beneficiaries.

<sup>35</sup>U.S. General Accounting Office, *Major Management Challenges and Program Risks: Department of Health and Human Services*, [GAO-01-247](#) (Washington, D.C.: Jan. 2001).

<sup>36</sup>U.S. General Accounting Office, *Balanced Budget Act: Any Proposed Fee-for-Service Payment Modifications Need Thorough Evaluation*, [GAO/T-HEHS-99-139](#) (Washington, D.C.: June 10, 1999).

<sup>37</sup>U.S. General Accounting Office, *Medicare: HCFA Faces Challenges to Control Improper Payments*, [GAO/T-HEHS-00-74](#), (Washington, D.C.: Mar. 9, 2000).

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access problems, this information is somewhat dated.<sup>38</sup> Informed decisions about appropriate payment rates and rate changes cannot be made unless policymakers have detailed and recent data on beneficiaries' access to needed services.

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Mr. Chairman, this concludes my prepared remarks. I will be happy to answer any questions you or the Subcommittee Members may have.

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## Contact and Acknowledgments

For further information regarding this testimony, please contact me at (312) 220-7600. Sheila Avruch, Hannah Fein, Sandra Gove, Joy Kraybill, and Craig Winslow made contributions to this statement.

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<sup>38</sup>U.S. General Accounting Office, *Medicare Physician Payments: Spending Targets Encourage Fiscal Discipline, Modifications Could Stabilize Fees*, [GAO-02-441T](#), (Washington, D.C.: Feb. 14, 2002).

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# Related GAO Products

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*Medicare Outpatient Drugs: Program Payments Should Better Reflect Market Prices.* [GAO-02-531T](#). Washington, D.C.: March 14, 2002.

*Medicare Physician Payments: Spending Targets Encourage Fiscal Discipline, Modifications Could Stabilize Fees.* [GAO-02-441T](#). Washington, D.C.: February 14, 2002.

*Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost.* [GAO-01-1118](#). Washington, D.C.: September 21, 2001.

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*Medicare Management: CMS Faces Challenges to Sustain Progress and Address Weaknesses.* [GAO-01-817](#). Washington, D.C.: July 31, 2001.

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*Medicare: Comparative Information on Medicare and VA Patients, Services, and Payment Rates for Home Oxygen.* [GAO/HEHS-97-151R](#). Washington, D.C.: June 6, 1997.

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